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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,786	01/26/2004	Thomas William Deveney	SAR 15036	9752

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,786	DEVENEY ET AL.	
	Examiner	Art Unit	
	James W. Rogers	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 01/26/2004 has been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,902,598) in view of DePrince et al. (US 4,898,733) in view of Guo et al. (US 2002/0102307 A1) and in further view of Lyles et al. (US 6,340,360 B1).

Chen discloses a controlled release drug delivery system comprising an inflexible sleeve with a 1st controlled-release layer (10) and a 2nd controlled release layer (15) where the controlled release layers are deposited within the sleeve and are spaced apart from one another, defining a drug-retaining region (5) in the space between the

controlled-release layers and admit, in a controlled manner by body fluid affecting the rate of dissolution, a delayed drug release into an ambient environment. See col 8 lin 32-37 and fig 1. Chen also discloses that the controlled-release layers undergo dissolution by exposure to a bodily fluid with the effect of a delayed drug release and where the controlled release layers control a rate of diffusion of body fluid into and out of the drug-relating region. See col 7 lin 1-10 and col 8 lin 32-37. Chen also discloses an inner surface of the sleeve with a first sealing surface (19) near the first end and second sealing surface (18) near the second end, a marginal region of the first controlled-release layer (10) abutting the first sealing surface and a marginal region of the second controlled release layer (15) abutting the second sealing surface (18) at least one dose being disposed in drug delivery region (5), at least a dose of drug being disposed adjacent of the 1st end of the sleeve outside of drug-retaining region, at least a dose of drug being disposed adjacent of the second end of the sleeve outside of drug-retaining region, see fig 1. Chen also discloses that the drug delivery device can comprise cellulose acetate butyrate, see col 9 lin 26.

Chen does not disclose that the sleeve is open at both ends nor does Chen disclose a first cap having an open center being received by the first end of a sleeve and abuts a marginal region of a first controlled release layer and a second cap having an open center being received by the first end of a sleeve and abuts a marginal region of a first controlled release layer, and Chen does not disclose a dose unit of a drug disposed adjacent the first end of a sleeve outside of a drug retaining region and a dose unit of a drug disposed adjacent the second end of a sleeve outside of a drug retaining

region wherein the drug contained in the dose unit is disposed inside the drug retaining region differ from the drug of at least one of the dose units disposed outside the drug retaining region and wherein the drug of each dose unit disposed outside the drug-retaining is different from one another.

DePrince et al. discloses a layered compression molded device for the sustained release of a beneficial agent with a sleeve that is open at both ends. See col 6 lin 62-65.

Gua discloses a sustained release drug delivery device with a first cap having an open center and being received by the first end of a sleeve and abuts a marginal region of a controlled release layer and a second cap which has an open center and being received by the first end of a sleeve and abuts a marginal region of a controlled release layer. See [0057] and fig 4.

Lyles discloses a dose unit of a drug disposed adjacent to the first end of a sleeve outside of a drug retaining region and a dose unit of a drug disposed adjacent to the second end of a sleeve outside of a drug retaining region wherein the drug contained in the dose unit is disposed inside the drug retaining region differ from the drug of the dose units disposed from one another. See col 13 lin 35-50 and fig 2. In another embodiment the drug can contain multiple reservoirs each containing a different drug. See col 13 lin 51-55.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Chen describes a controlled release drug delivery device composed of an

inflexible sleeve with a first and second controlled release layer with a space between them defining a drug space or core, the controlled release layers area absorbed by bodily fluids thus controlling the release rate. The DePrince patent discloses a controlled release device with two open ends, while the Guo patent discloses a drug delivery system with two caps having an open center and abuts to a marginal region of a controlled release layer and the Lyles patent teaches a dose unit in which the drug is disposed adjacent to first and second end of a sleeve outside of a drug retaining region. Therefore it would have been obvious for a skilled artisan to combine the teaching of Chen, DePrince, Guo and Lyles in order to make the device as claimed. The motivation to combine the above documents would be a drug delivery device composed of an inflexible sleeve with a 1st and 2nd controlled release layers on opposite sides of the dosage unit which is caped with a 1st and 2nd end-cap both with openings with drug(s) that can be dispensed within the sleeve between the controlled release layers or outside of the sleeve. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER